

Applicants: P. Bonutti and J. Hawkins
Application No.: 09/992,211
Examiner: M. Thaler

Remarks

Claims 57-62, 64-73, 75, and 77-89 are pending in the application and are presented for the Examiner's review and consideration. Claim 66 has been amended and claims 80-89 have been added. Applicants believe that the claim amendment, additions, and the accompanying remarks serve to clarify the present invention and are independent of patentability. Accordingly, Applicants respectfully submit that they do not limit the range of any permissible equivalents.

Claims 66 and 70 were rejected under 35 U.S.C. § 102(e) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,183,4443 to Kratoska *et al.* ("Kratoska"). Claims 66, 70, and 71 were rejected under 35 U.S.C. § 102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,312,417 to Wilk ("Wilk"). For the reasons set forth below, Applicants respectfully submit that the rejected claims are not taught or suggested by Kratoska or Wilk.

Kratoska discloses an expandable introducer sheath. An expandable introducer sheath 200 includes an elongated flexible shaft 206 extending between distal end 202 and proximal end 204. (Column 24, lines 3-6). At least one rib 207 extends longitudinally on an inner wall of the sheath shaft 206. (Column 24, lines 9-10, and FIGS. 7A-7C). The rib abuts an outer wall of the intravascular device 214 thereby providing extra spacing between an inner wall of the sheath shaft 206 and an outer wall of the intravascular device 214. (Column 24, lines 51-54). This spacing or opening permits blood pressure monitoring, blood removal, blood delivery, or drug infusion, through the sheath via the hub 208. (Column 24, lines 54-56).

Although only one rib is shown in the figures, Kratoska discloses that several ribs may extend longitudinally along an inner wall of the sheath shaft 206. (Column 24, lines 56-61). "The shaft 206 of the expandable introducer sheath 200 is made of an elastomeric tubing material ... that is capable of being radially expanded by mechanically applied pressure within the sheath shaft 206." (Column 24, lines 23-29).

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The Examiner states that "Kratoska et al., in figures 7A-7C, show tubular sheath 200 and an array of filaments 207 (as described in Col. 24, lines 57-61) which extend along an inner side of the passage of the sheath 200. . . . Filaments 207 are 'filaments' since they are thin and elongated. Alternatively, it would have been obvious that ribs 207 are 'filaments' since they are thin and elongated.

As disclosed, the Kratoska sheath includes at least one rib extending longitudinally on the inner wall of the sheath. Specifically, as shown in FIG, 7B and 7C, the rib is a part of the sheath, being an extension or projection of the inner surface of the sheath. As such, the rib is necessarily made of the same material as the sheath.

In contrast and as disclosed in the specification, a cannula 10 according to one embodiment of the present invention includes an expanding portion 12 with a plurality of filaments or wires 16 that are surrounded by an overlying elastic sheath 18. Specification, p. 7, lns. 15-20. The wires 16 engage the circumferential inner surface 56 of the sheath. *Id.*, p. 10, lns. 8-9.

Thus, it is seen that the wires 16 have outer surface portions 60 disposed radially inwardly in the cannula 10 and forming contact surfaces for surgical instruments and the like inserted through the central instrument passage 20 of the cannula. The sheath 18 has an outer circumferential surface 54 engaging tissue when the cannula 10 is in use. The wires 16 block engagement of instruments inserted through the central instrument passage 20 of the cannula 16 with the elastic sheath 18. The sheath 18 blocks engagement of tissue with the wires 16, and the sheath and the wires block engagement of tissue with any instruments inserted through the cannula 10. *Id.*, p. 13, lns. 3-13.

Applicant submits that Kratoska does not disclose each and every element as set forth in claim 66, either expressly or inherently. For example, Kratoska does not disclose that the rib inhibits or blocks contact between an object inserted in the passage and the sheath. The Kratoska rib is disclosed as only forming a space between an inner wall of the sheath shaft and an outer wall of the intravascular device for the monitoring blood pressure and/or the insertion or removal of fluid from the body of the patient. As such, Kratoska does not expressly disclose that the rib blocks contact between the inner surface of the sheath and the outer surface of the intravascular

Applicants: P. Bonutti and J. Hawkins

Application No.: 09/992,211

Examiner: M. Thaler

device.

Applicant further submits that it would not be inherent that rib blocks contact between the inner surface of the sheath and the outer surface of the intravascular device. Kratoska discloses that "[t]he sheath 200 should be lubricously coated (by silicone or hydrophilic lubrication) on its inner surface and outer surface to permit smooth movement of any intravascular device relative to the sheath. . . . In addition, a longitudinal stiffening member such as an elongate wire may be embedded in a wall of the sheath 200 or within a rib on the inner wall of the sheath 200. The stiffening member would provide additional support to prevent potential elongation of the sheath 200 when attempting to push a guide catheter (or other intravascular device) through the sheath 200. The potential for elongation of the sheath 200 occurs because of the friction caused between the outer surface of the guide catheter and the inner surface of the sheath 200 when the guide catheter is pushed through the sheath 200." (Column 25, lines 45-66.)

Accordingly, Kratoska expressly discloses that the inner surface of the sheath and the outer surface of the guide catheter will be in contact and provides specific methods for decreasing the friction and preventing elongation of the sheath caused by such contact. As such, Kratoska teaches away from the rib blocking contact between the inner surface of the sheath and the outer surface of the guide catheter. Accordingly, Applicant submits that Kratoska does not inherently disclose that the rib blocks contact between the inner surface of the sheath and the outer surface of the intravascular device.

In order to clarify the present invention, claim 66 now recites that the "array of filaments blocks contact between an object inserted in the passage and said sheath." Support for this amendment can be found in the specification, page 13 lines 9-11. As the term "block" is used in the specification, there is no contact between the sheath and an object inserted in the passage. See, e.g. Specification, page 8 lines 9-13 ("If not enough wires 16 are used, an instrument (trocar, insert, scope, etc.) inserted through the passage 20 when the cannula 10 is expanded will contact the elastic sheath 18 rather than the wires 16, at locations between the wires."). Although Applicants respectfully submit that "inhibits" also distinguished the claim from the prior art, the

Applicants: P. Bonutti and J. Hawkins
Application No.: 09/992,211
Examiner: M. Thaler

amendment to claim 66 is intended to clarify the claim, using terminology presented in the specification. No new matter has been added.

With respect to the alternate obviousness rejection, Applicants respectfully submit that the Examiner has not established a *prima facie* case of obviousness. As noted above, Kratoska does not teach or suggest all of the claim elements, and there is no motivation or suggestion to modify the reference.

In light of the foregoing, amended independent claim 66 is respectfully submitted to be patentable over Kratoska. As claim 70 depends from claim 66 and necessarily includes all the elements of its base claim, Applicants respectfully submit that claim 70 is also allowable over Kratoska at least for the same reasons.

As previously noted, the Examiner also rejected independent claims 66 as anticipated by, or in the alternative, as obvious over Wilk.

Wilk discloses a laparoscopic cannula or trocar sleeve for use in laparoscopic surgery. (Column 3, lines 32-34). The cannula comprises a rigid tubular member 12 with an insufflation portion component 14 at a proximal end and an expandable receiver portion 16 at a distal end. (Column 3, lines 34-36). Receiver portion 16 includes an elastic or pleated web 18 provided along with an inner surface with a plurality of longitudinal extending resilient ribs 20. (Column 3, lines 39-42). Ribs 20 have an internal spring bias tending to maintain the ribs in a straightened configuration (FIG. 1). (Column 3, lines 42-44).

Upon pulling of a severed organ or organ part into the distal end of receiver portion 16, ribs 20 expand outwardly, thereby permitting a surgeon to pull the severed organ into the web 18. (Column 3, lines 44-47). Upon drawing of the severed organ into receiver portion 16, the entire cannula is withdrawn from the abdominal wall of the patient. (Column 2, lines 52-54). Receiver portion 16 expands from a substantially cylindrical insertion configuration shown in FIG. 1 to an expanded cubshaped pocket shown in FIG. 2. (Column 3, lines 36-39.)

The expandable receiver portion of the Wilk cannula has two components, a web provided along with a plurality of longitudinal extending resilient ribs. In use ribs expand

Applicants: P. Bonutti and J. Hawkins
Application No.: 09/992,211
Examiner: M. Thaler

outward, forming the receiver portion into a cupshape, allowing the surgeon to draw the severed organ into the web. The web supports the severed organ for removal from the patient abdomen. As such, Wilk discloses that the severed organ, the object inserted into the passage, is in contact with the web, the sheath.

In contrast, as noted above, claim 66 recites, *inter alia*, a sheath having an array of filaments on an inner surface "such that said array of filaments blocks contact between an object inserted in the passage and said sheath." As used in the specification, the blocking effect of the array of filaments prevents contact between the inserted object and the sheath. Wilk discloses that the severed organ is drawn into the web, wherein the web supports the severed organ for removal from the patient's abdomen. As such, Wilk does not expressly disclose that the ribs block contact between the inner surface of the web and the outer surface of the severed organ.

Applicants further submit that it would not be inherent that the ribs block contact between the inner surface of the web and the outer surface of the severed. Wilk discloses that the "ribs 20 may alternatively be attached to the outer surface of web 18." (Column 3, lines 56-57.) In such a configuration it would be impossible for the ribs to block contact to the inner surface of the sheath.

Additionally, the Wilk device is intended to remove a severed organ from the abdomen of a patient. The severed organ has a conformal non-uniform cross section. It is inherent the severed organ will conform to the inner surface of the receiving member, conforming over the ribs to contact the web.

Furthermore, the webbing is made of an elastic material and the ribs are resilient. It is therefore inherent that the inner surface of the receiving portion, the web and the ribs, will conform around the severed organ to grip the organ for removal. Accordingly, Applicants submit that Wilk does not inherently disclose that the ribs block contact between the inner surface of the web and the outer surface of the severed organ.

With respect to the alternate obviousness rejection, Applicants respectfully submit that the Examiner has not established a *prima facie* case of obviousness. As noted above, Wilk does

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Application No.: 09/992,211
Examiner: M. Thaler

not teach or suggest all of the claim elements. Additionally, there is no motivation or suggestion to modify the reference. Wilk teaches that the severed organ is drawn into the web for removal and that the ribs can be on the inner surface or the outer surface of the web. As such there is no motivation or suggestion to modify Wilk such that the ribs block the severed organ from contacting the web. Furthermore, Applicants are unaware how Wilk can be modified such that the ribs prevent a conformal object from contacting the web.

In light of the foregoing, amended independent claim 66 is respectfully submitted to be patentable over Wilk. As claims 70 and 71 depend from amended claim 66 and necessarily include all the elements of their base claim, Applicants respectfully submit that claims 70 and 71 are also allowable over Wilk at least for the same reasons.

Claims 67-69 were objected to as being dependent upon a rejected base claim. As claims 67-69 depend from claim 66, which is believed to be allowable, Applicants hereby respectfully request reconsideration and withdrawal of the objection.

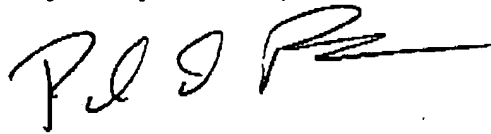
Finally, Applicants acknowledge with appreciation the continued allowance of claims 57-62, 64, 65, 72, 73, 75, and 77-79.

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

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Application No.: 09/992,211
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Please charge the required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket no. 780-A02-003-2).

Respectfully submitted,



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